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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,561	10/17/2003	David W. Burke	7404-556	2403

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EXAMINER	
SODERQUIST, ARLEN	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/688,561	BURKE ET AL.	
	Examiner	Art Unit	
	Arlen Soderquist	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,19 and 21* is/are rejected.

7)☒ Claim(s) *18 and 20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6-4-08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 6). Other: Examiner was not able to find copies of the references..

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Blackmer (US 3,661,748). In the patent Blackmer teaches sensor fault sensing instrumentation. The electrochemical sensor system (to sense pH, pO_2, and pCO_2 values in blood samples) includes an electrode system for disposition in a conducting fluid that is arranged to produce a dc signal as a function of a parameter of interest sensed by the electrode system. There is DC circuitry responsive to the dc signal from the electrode system for producing an output indicative of the parameter of interest sensed by the electrode system. The system for detecting a sensor fault consists of a means for providing an electrical connection to the conducting fluid, means to apply an AC signal to the electrical connection, an ac signal detector connected to the DC circuitry, and a threshold circuit responsive to the output of the AC signal detector for providing an output signal indicative of a fault in the electrochemical sensor system when the AC signal detector has an output that differs by a predetermined amount from a normal value. Column 3, lines 14-21 teach that the AC frequency is 170 Hz. Column 4, lines 46-64 teaches that the embodiment shown provides fault detection for three different types of electrochemical sensors. Additionally in the preferred embodiment, the phase angle is controlled to detect only one part of the signal.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-17, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over White (US 5,352,351) in view of Blackmer as explained above. In the patent White teaches a biosensing meter receives a sample strip that includes electrically isolated sense and excitation electrodes bridged by a reaction zone. When a drop of biological sample fluid is placed in the reaction zone, a plurality of fail/safe tests are performed. A drop size test is performed by a circuit that detects the size of the drop placed in the reaction zone. The circuit both detects that a drop has been placed in the reaction zone and further measures a test current level, after a delay, to determine that the drop size is sufficient to enable hydration of reactants in the reaction zone. Subsequently, during the reaction, a "delta" current change is measured at succeeding sample time. This test measures the difference between succeeding current samples during a measurement time. If each succeeding sample is not less than preceding sample by a delta value, a determination is made that the current is not monotonically decreasing and the test is aborted. At the termination of the measurement time, a current sum test is performed wherein a processor calculates a linear sum of all sample test currents and calculates a ratio between that sum and the last current sample. If that ratio matches a pre-calculated constant for the Cottrell relationship, then it is known that the measurement values exhibit the Cottrell relationship. Figure 7 shows the flow chart for this part of the failsafe test. During the time when current values 82, 84, 86, etc. of figure 5 are being measured, a "delta" fail/safe calculation occurs after the second current measurement and then after each succeeding current measurement (box 120). In essence, it is known that if trace (78, figure 5) follows a Cottrell curve, it monotonically decreases and each succeeding current measurement is less than a preceding current measurement by at least a predetermined delta fail/safe threshold value. That value is obtained from ROM key 48 and is accessed by microprocessor 42. As shown in decision box 120, microprocessor 42 determines that each succeeding sense current i_k is less than or equal to a preceding sampled current value (i_{k-1}) plus the delta fail/safe threshold value. If a succeeding sense current value does not meet that test, an abort message is sent to the user (via display 44) based on the determination that the current waveform is not exhibiting an expected monotonic relationship. This test is repeated for each succeeding current sample, including last current sample 88. Until then, the procedure

repeats as shown by decision box 124. Once current measurement 88 has been taken, the procedure moves to a "current sum" fail/safe determination. The current sum fail/safe procedure performs another check on the Cottrell response during the measurement period. When the final current sample is acquired, it is multiplied by two constants (i.e. values) that are accessed by microprocessor 42 from ROM key 48. The results of the multiplication are then used as two limit values against which a sum of all of sensed currents 82, 84, 86 etc. is tested. If the sum falls between the two limits, it is known that trace 78 follows the Cottrell relationship. These actions are illustrated in boxes 122, 124, 126 and 128 in figure 7. Current sum I_{sum} is calculated as shown in box 122 where i_k is one of m current samples. The basis for the current sum fail/safe is the ratio shown in column 8, line 38-44 (expression D). Considering expression (D), it can be concluded that if a trace has Cottrell behavior, then the ratio r shown in equation A calculated with this trace's currents must be equal to $r_{cottrell}$. Inversely, if a trace has non-Cottrell behavior, then the corresponding ratio r from equation (A) is different from $r_{cottrell}$. An allowance is made for some variability and this ratio becomes the test to see if the response is the correct type of response or if the result should be disregarded.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to adapt the failsafe procedure of White to incorporate the AC fault measurements of Blackmer because of the ability to detect faulty sensors in a variety of formats as taught by Blackmer.

5. Claims 18 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The art of record fails to teach or fairly suggest the method as claimed.

6. Applicant's arguments filed May 22, 2008 have been fully considered but they are not persuasive. Applicant has basically argued that the term “abused” has been defined by applicant’s specification to be something different than the fault(s) detected in the Blackmer reference. In the last part of the section quoted the test is such that it will abort the measurement process or at least warn that the test results may not be accurate when the “abused sensor” is inserted into the test meter. The section referred to by applicant needs to be considered in light of the entire specification. The following are two paragraphs reproduced, with added emphasis,

from the instant specification that have bearing on the meaning of what applicant has pointed to in the response. The first paragraph below is the first paragraph of page 10 and the first paragraph of the detailed description. The second paragraph is the last paragraph of page 57 and the last paragraph of the detailed description.

> " For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings, and specific language will be used to describe that embodiment. ***It will nevertheless be understood that no limitation of the scope of the invention is intended. Alterations and modifications in the illustrated device, and further applications of the principles of the invention as illustrated therein, as would normally occur to one skilled in the art to which the invention relates are contemplated, are desired to be protected.*** In particular, although the invention is discussed in terms of a blood glucose meter, it is contemplated that the invention can be used with devices for measuring other analytes and other sample types. Such alternative embodiments require certain adaptations to the embodiments discussed herein that would be obvious to those skilled in the art."
>
> " While the invention has been illustrated and described in detail in the drawings and foregoing description, ***the description is to be considered as illustrative and not restrictive in character. Only the preferred embodiment, and certain other embodiments deemed helpful in further explaining how to make or use the preferred embodiment, have been shown. All changes and modifications that come within the spirit of the invention are desired to be protected***."

From these sections it is abundantly clear that the specification is intended to not restrict the scope of the invention/claims. Thus, the first paragraph of page 43 that applicant has referred to is not limiting, but rather illustrative of sensor conditions that would prevent an accurate analysis from being obtained and for which one would want to either abort the analysis or indicate that the analysis is not accurate. With that in mind, one of skill in the art would have certainly recognized that the conditions of Blackmer would have prevented one from making an accurate determination of the analyte. Therefore, they would fit within the scope that one of ordinary skill in the art would have considered to be an "abused" sensor since they would prevent an accurate determination from being carried out. Additionally the first paragraph of page 43 does not say that the three conditions listed are the only conditions that are considered to be "abused sensors". Thus if applicant wishes to be limited to those three conditions, the phrase "abused sensor" should be replaced with language that clearly limits the scope to only those conditions. Since Blackmer appears in both rejections and is the reference that provides what the White reference

is lacking in the obviousness rejection, the current rejections are either anticipatory of or make obvious the scope of the current claims.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571)272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Arlen Soderquist/
Primary Examiner, Art Unit 1797